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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,636	02/02/2001	Maryellen L. Giger	200977US-20	5322

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EXAMINER

AZARIAN, SEYED H

ART UNIT PAPER NUMBER

2625

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/773,636

Applicant(s)

GIGER ET AL.

Examiner

Seyed Azarian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10.12.14.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. Applicants' amendment filed, 3/1/2004, has been entered and made of record.
2. Applicants' arguments with regards to Claims 1-37 have been fully considered but they are not persuasive.
3. Applicants' argues in essence regarding claim 1, that Giger does not teach, "comparing the computed features characteristic to corresponding computed feature characteristics derived from images in a known image data".

Contrary to the applicants' assertion, Giger discloses the various features (characteristic) from suspicious region in both the processed images and the original images, and determination of appropriate cutoff values for the extracted features in merging the individual features measures to classify each suspicious region as "mass" or "non mass". A region containing the suspected lesion is selected in the original and processed images (column 5, lines 15-25), also cumulative histogram can be used to characterized each feature and determine an appropriate cut off value for that feature, cumulative histogram for both actual-mass detection and non-mass detection were calculated using "database 308 mammograms" (known diagnoses), (column 7, lines 35-44), and finally Fig. 11, extracted lesion various features (characteristics) can be used either separately or merged (computing and comparing), into a likelihood of being an actual mass. Fig. 12 artificial neural network for merging the features into a likelihood of whether or not the features represent a mass or a falls-positive detection (column 8, lines 47-60).

In response to applicant's arguments regarding claim 4, the examiner conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight

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reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 5-37, are rejected under 35 U.S.C. 102(b) as being anticipated by Giger et al (U.S. 5,832,103).

Regarding claim 1, Giger et al discloses a method for computer assisted interpretation of a medical image, comprising, obtaining image data representative of a medical image, computing at least one feature characteristic of the image data (Fig. 1, column 4, lines 3-15, detection and classification of masses and likelihood of malignancy);

comparing the computed feature characteristic to corresponding computed feature characteristics derived from images in a known image data set having known diagnoses (column 5, lines 16-26, extraction of various features and classify each region, also column 7, lines 35-44, cumulative histogram can be used to characterized each feature and determine an appropriate cut off value for that feature, cumulative histogram for both actual-mass detection and non-mass detection were calculated using “database 308 mammograms” (known diagnoses));

selecting image data from images of the known image data set having corresponding computed feature characteristics similar to the feature characteristics computed in the computing step column 6, lines 28-39, calculating the area and similarity);

displaying at least one of the selected image data and the obtained image data (Fig. 4A and 4D column 4, lines 55-67, and column 11, lines 36-45, refer to displaying mammograms).

Regarding claim 2, Giger et al discloses a method of Claim 1, further comprising: using a graphical user interface to display the image data (column 11, lines 36-45, display system).

Regarding claim 3, Giger et al discloses the method of Claim 1, further comprising, displaying a first indicator identifying which of the selected image data correspond to malignant lesions and a second indicator identifying which of the selected image data correspond to benign lesions (Fig. 4A-4D, column 4, lines 55-67, position of subtle mass lesion and column 5, lines 15-26, the suspected lesion).

Regarding claim 5 Giger et al discloses the method of Claim 1, further comprising; displaying the selected image data with or without an ASCII or numerical indicator corresponding to the computed feature characteristics derived from the images in the known image data set (column 5, lines 56 through column 6, lines 9, computer reported suspicious region as misalignment artifact).

Regarding claim 6, Giger et al discloses the method of Claim 2, further comprising; displaying multiple views of the same obtained image data in the graphical user interface (Fig. 27, column 3, lines 53-56, refer to individual performance).

Regarding claim 7, Giger et al discloses the method of Claim 2, further comprising:
using a selection mechanism in the graphical user interface to select at least one feature characteristic for use in the computing step (Fig. 11, column 8, lines 47-59, graph showing the average values for the various features).

Regarding claim 8, Giger et al discloses the method of Claim 2, further comprising:
using a region in the graphical user interface to display an enlarged view of the obtained image data relative to the displayed multiple views (column 11, lines 21-29, detection result are either superimposed onto mammograms and display).

Regarding claim 9, Giger et al discloses the method of Claim 8, further comprising:
using an adjustment mechanism in the graphical user interface to adjust sharpness and brightness of the enlarged view of the obtained image data (Fig. 17A, column 9, lines 28-39, refer to high-resolution).

Regarding claim 11, Giger et al discloses the method of Claim 1, wherein the computing step comprises; computing a margin characteristic feature including at least one of a speculation measure and margin-sharpness measure (Fig. 25, column 41-50, information of speculation).

Regarding claim 12, Giger et al discloses the method of Claim 11, wherein the computing step comprises; computing the speculation measure by analysis of radial edge gradients, including evaluating an average angle by which a direction of a maximum gradient at each point along a margin of a mass within the image data deviates from a radial direction from a

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geometric center of the mass to a point on the margin to determine the speculation measure (Fig. 22, column 10, lines 1-19, calculating the maximum gradient and determining the angle to distinguish speculated).

Regarding claim 13, Giger et al discloses the method of Claim 12, wherein the computing step further comprises; calculating a normalized edge-gradient distribution for a neighborhood of a grown region of the mass with respect to the radial direction as the speculation measure; and representing the computed speculation measure by a full width at half-maximum (FWHM) of the calculated normalized edge-gradient distribution (Fig. 27, column 10, lines 51-64, FWHM feature).

Regarding claim 15 Giger et al discloses The method of Claim 1, wherein the computing step comprises; computing a density characteristic feature including at least one of average gray level, contrast and texture (column 4, lines 20-32, each pixel corresponds to a texture in order to enhance asymmetries between the left and right mammograms followed by multi-gray-level).

Regarding claim 17, Giger et al discloses the method of Claim 15, wherein the computing step comprises; determining a difference between an average gray level of a grown mass within the image data and an average gray level of surrounding areas within the image data to determine the contrast (column 4, lines 26-42, refer to contrast).

Regarding claim 18, Giger et al discloses the method of Claim 15, wherein the computing step comprises; determining a standard deviation of an average gradient within a mass within the image data to determine the texture (column 8, lines 34-46, ration of standard deviation).

Regarding claim 19, Giger et al discloses the method of Claim 1, wherein; the comparing step comprises identifying plural retrieved known images defining a distribution of known malignant and benign abnormalities with respect to the computed feature characteristic; and the displaying step comprises displaying symbols representing a continuum of the known images ranging from malignant to benign abnormalities as a function of a value of the computed feature characteristic, and displaying a symbol representative of a position of candidate abnormalities in relation to the symbols of the continuum based on similarity of the computed feature characteristic and the corresponding feature characteristic existing in the known images (Fig. 27, column 11, lines 46-55, likelihood of malignancy and display system).

Regarding claim 21, Giger et al discloses the method of Claim 20, further comprising; applying the computed at least one feature characteristic to an artificial neural network; and determining a likelihood of malignancy based on an output unit of the artificial neural network (Fig. 12, column 3, lines 8-13, artificial neural network).

Regarding claim 22, Giger et al discloses the method of Claim 21, wherein the applying step comprises; applying the computed at least one feature characteristic to the artificial neural network configured as a three-layered, feed-forward, back propagation artificial neural network (Fig. 3, see claim 21 and column 4, lines 43-53, refer to various levels).

Regarding claim 23, Giger et al discloses the method of Claim 22, further comprising; providing the three layers of the artificial neural network as plural input units, plural hidden units and one output unit, respectively (Fig. 11, column 8, lines 47-59, artificial neural network and hidden unit).

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Regarding claim 33, Giger et al discloses a method for intelligent search of a known database for interpretation of medical images, comprising; generating image data from images derived from patients; computing feature characteristics of said image data; comparing said feature characteristics to computer-extracted feature characteristics of images in a known image data set; and displaying similar lesions with or without computer analysis output based on said comparison results (column 11, lines 14-28, the lesion extraction).

Regarding claims 10, 14 and 16, it recites similar limitation as claims 5, 12 and 15, are similarly analyzed.

Regarding claims 24-27 and 34, it recites similar limitation as claims 1, 3-4 and 15, are similarly analyzed.

Regarding claims 20 and 28-31, it recites similar limitation as claims 12, 21 and 22, are similarly analyzed.

Regarding claims 32, 35-37, it recites similar limitation as claims 1, 8 and 17, are similarly analyzed.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 4, is rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al (U.S. patent 5,832,103) in view of Nishikawa et al (U.S. patent 6,058,322).

Regarding claim 4, Giger et al is silent about "color" On the other hand Nishikawa et al in the same field of diagnosis system teaches (Fig. 22, column 31, lines 41-50, first color at appropriate locations on each line of diseases and also second color on the same line as that marked with a pen of the first color).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention was made, to modify Giger et al invention according to the teaching of Nishikawa et al because it is conventional techniques that provides visual perception that enable one to distinguishing particular or identical image from each other, which can easily be implements in tracking object device for desirable image and improve accuracy.

Other prior art cited

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. patent (6,185,320) to Bick et al is cited for method and system for detection of lesions in medical images.

U.S. patent (6,138,045) to Kupinaki et al is cited for method and system for the segmentation and classification of lesions.

U.S. patent (5,537,485) to Nishikawa et al is cited for method for computer-aided detection of clustered microcalcifications from digital mammograms.

U.S. patent (5,452,367) to Bick et al is cited for automated method and system for the segmentation of medical images.

U.S. patent (5,984,870) to Giger et al is cited for method and system for the automated analysis of lesions in ultrasound images.

Conclusion

9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (703) 306-5907. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta, can be reached at (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Seyed Azarian

Patent Examiner

Group Art Unit 2625



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May 20, 2004